REMARKS

Claims 1-39 were previously pending in the present application. Claim 39 is hereby canceled. The second occurrence of claim "20" is hereby renumbered to 30, and claims 37 and 38 are hereby renumbered to 36 and 37, respectively. Claims 1, 22, 29, 35 and original claim 37 (now claim 36) are hereby amended. Thus, claims 1-37 remain pending as renumbered and amended.

Claim Objections

Claims 18 and 21-35 were objected to for various informalities stated in paragraph 1 of the above-noted Office Action.

With regard to the antecedent basis issue raised with respect to claim 18, "the mouth" recitation is properly preceded by the phrase "an open mouth" in claim 17 from which claim 18 depends. No correction is thus needed.

Regarding claim 22, the claim properly recites a "scoop opening at the side of the needle". There is no scoop opening in the hub and thus the suggested change would not be appropriate. No correction is thus being made.

With regard to claims 22 and 35, the language "one or more" has been replaced with "at least one" as suggested. The other noted objection to claim 22 with regard to "the hub opening" has been obviated by other amendments made to this claim.

Regarding claim 29, the phrase "the position of" has been deleted in response to the noted objection.

Regarding claim 31, the term "device" at line 10 has been replaced with "syringe" as suggested.

Also, misnumbered claims 20 and 37-38 have been renumbered to claims 30 and 36-37, respectively, with original claim 39 being canceled.

Thus, all of the objects raised in paragraphs 1 and 2 of the Office Action have been addressed.

Claim Rejections

The above Office Action recites numerous rejections based on an array of prior art references (seven patents in all). All of these art rejections are believed to be overcome by virtue of at least one distinctive feature of the present invention pertaining to the sample passageway for passing specimens inside the hub from above the floor of the collection well. This feature of the invention provides functional benefits, arising from structural improvements, that are not disclosed or suggested by the numerous prior art references cited. This subject matter has now been incorporated into every claim, by virtue of the amendments made to all independent claims (claims 1, 22, 35 and 36). Therefore, in light of the above amendments and the following discussion, reconsideration of the claims is respectfully requested.

1. Novelty

Specifically, claim 1 (and thus claims 2-21 and 31-34) and claim 22 (and thus claims 23-30) are hereby amended to recite a sample passageway opening inside the hub in spaced relation to the floor of the collection well such that a specimen can pass through the needle into the hub and be deposited in the collection well from above the floor. Claim 35 and claim 36 (and thus claim 37) are hereby amended to include similar language.

The DeVries, Ellingson and Markham patents were each cited to support novelty-based rejections. The DeVries patent was cited with regard to claims 1-3, 6-8 and 16-17, the Ellingson patent was cited with regard to claims 22, 24-26, 36 and 38 and Markham was cited with regard to claims 22 and 31-34. However, since all of the claims require a sample passage as stated above, and since all of these patents (and the others cited) lack such a sample passage, the cited patents will be addressed herein without regard to particular claims.

Specifically, the DeVries patent teaches a biopsy device with an annular seal (O-ring) 60 that can be rolled back by the physician to expose a radial port 72 to vent the interior of the hub 40 to ambient, and thereby disrupt the vacuum. The port is a vent, and does not constitute part of the passageway for the sample specimens. The sample passageway extends from the central tapered passage 62 to the central opening 64 that receives the needle 70, which is hollow to the tip. The specimens are thus drawn through the needle and directly up into the hub 40 through the passage 62 and opening 64. The specimens do not pass through the port 72, which therefore it does not correspond to the claimed opening in the sample passageway, nor are the specimens deposited from above the floor of the collection well as now claimed.

Regarding the Ellingson patent, as an initial matter, the disclosed device is a "drainage catheter" for the "therapeutic or diagnostic aspiration of fluid or air from the thoracic or abdominal region" (see Abstract) and as such the disclosed device was not intended to address collection of sample specimens. Consequently, the device lacks both the structure and resulting benefits provided by the present invention. For example, the disclosed device has no "collection well" as required by the claims. Instead, the aspirated fluid or air simple passes from the device through side port 69. Thus, the device does not disclose a sample passageway as claimed.

The aspiration device disclosed in the Markham patent uses a conventional needle 36 that has a widened female end that mounts onto a male end 34 of a stopcock body 30. Withdrawing the piston 22 creates a vacuum that extends through to the tip of the needle when the valve member 40 is opened. Closing the valve member before the needle is withdrawn from the sample site breaks the vacuum and prevents specimens from passing up into the valve or syringe barrel 12. However, if at all, the sample specimens would enter the collection area (presumably the female end of the needle) directly from the bottom. Thus, the sample passageway is not as claimed, which, for example, leaves the device more susceptible to sample loss through reflux into the needle should the vacuum not be

fully discharged before the needle is removed from the sample site. The notable difference between the sample passageways and collection areas of the present invention and the prior art, can be clearly seen by comparing FIG. 16 of the present application with FIG. 1 of the reference.

2. Non-obviousness

The rest of the rejections cited in the Office action were obviousness rejections based on the combination of one or more of these three base references together and/or with one or more of Banys, Visconti, Weis-Fogh or Dysarz. Specifically, claims 4-5 and 10-11 were rejected on the combination of DeVries and Dysarz; claims 12-13 were rejected based on DeVries and Weis-Fogh; claims 14-15 and 18 were rejected based on DeVries and Ellingson; claim 19 was rejected based on DeVries alone; claim 20 was rejected based on DeVries and Visconti; claims 22-28, 30, 36 and 38 were rejected based on Visconti and DeVries; claims 35 and 37 were rejected based on Ellingson alone; claims 29-30 were rejected based on Ellingson and Banys; claim 21 was rejected based on DeVries and Banys; and claim 27 was rejected based on Ellingson and Weis-Fogh.

Of these numerous obviousness rejections, only three independent claims are implicated, namely claims 22, 35 and 36 (as now numbered). Since claim 35 was rejected for being obvious in light of Ellingson alone, and since claim 35 now recites a sample passageway that opens to an interior of the collection well through an opening spaced from a floor of the collection well such that a specimen can pass through the needle into the hub and be deposited in the collection well from above the floor, this claim is believed allowable for the reasons discussed above. Again, the Ellingson reference teaches a catheter without a collection well, and thus does not disclose or suggest the sample passageway as claimed. Further, since all of the dependent claims are believed to be allowable for these reasons, the numerous rejections to the dependent claims (under both §§ 102 and 103) are not addressed on the merits herein.

With regard to the rejection of independent claims 22 and 36 based on the Visconti and DeVries combination, the DeVries reference has already been discussed in detail. Again, the port 72 noted in the Office action does not constitute part of the sample passageway such that it does not correspond to the claimed opening in the sample passageway. Nor are the specimens deposited from above the floor of the collection well as now claimed, but instead the specimens are simply drawn through the needle and directly up into the hub 40 through the passage 62 and opening 64. The Visconti reference does not fill in deficiencies of the DeVries reference. Contrary to the third sentence on page 14 of the Office action, Visconti does not disclose a biopsy device, but instead a catheter. As pointed out with respect to the Ellingson reference, the device thus does not address the issue of obtaining meaningful sample specimens. Consequently, certain structures need not be included in a catheter that would be necessary in a biopsy device, namely an area to collect the specimens, and a suitable passageway to transfer the specimens from the needle to the collection area. Since the Visconti completely lacks these structures, its combination with DeVries does not bring one any closer to arriving at the claimed invention. As such, amended claim 22 (like all other independent and dependent claims) is believed to be both novel and non-obvious over the cited art.

Accordingly, in light of the amendments and remarks made herein, the cited prior art is not believed to anticipate or render obvious the present invention as now claimed.

Conclusion

Accordingly, claims 1-37 as now amended are believed to be in allowable form in light of the above remarks. Allowance of these claims is thus respectfully requested.

Enclosed herewith is a time extension petition requesting a 1-month extension of the response deadline, and authorizing payment of the associated fee to be charged to Deposit Account No. 17-0055. No fees in addition are believed

necessary for consideration of this response. Should any additional fees be needed for full consideration of this amendment, please charge them to Deposit Account No. 17-0055.

Respectfully submitted,

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By: _____

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